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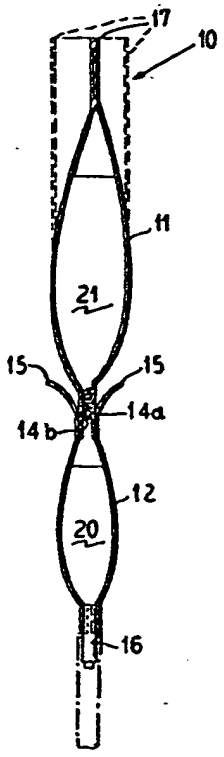
(54) Title: PREPARATION OF ELECTROLYTE SOLUTIONS AND CONTAINERS

(57) Abstract

Methods for preparing just before administration unit doses of therapeutic solutions which contain redox active unstable and/or diffusable metabolites such as a ketoacid, a sulfhydryl-containing amino acid, or carbon dioxide. The method involves preparing and storing an aqueous solution of stable components which may or may not contain carbon dioxide. A dry powder comprised of unstable components is also prepared and stored separately. These separate component compositions are packaged in, for example, individual chambers (11 and 12) of a common sealed container (10) which is so constructed as to permit the opening, by externally applied manual means or the like, of a passageway (14a and 14b) between such chambers (11 and 12) at the time when usage is contemplated. Thus, a fresh solution in desired full dosage form is preparable just before administration. Improved container structures for practice of this method are also provided.



CLAIMS

I claim:

1. A method for preparing a therapeutic aqueous solution which contains dissolved therein unstable metabolites, said method comprising the steps of:

(A) charging a first composition into a first chamber of a container,

(B) charging a second composition into a second chamber of said container,

each of said first and second chambers being hermetically sealed with said respective compositions therein, and said container being hermetically sealed with respect to each of said chambers, each of said chambers being in communicatable relationship with the other thereof while said container is in such sealed condition, and said container including means for externally producing communication between said respective first and second chambers,

(C) opening a communication pathway between said first and said second chambers,

(D) intermixing the first composition with the second composition within said sealed container, and

(E) administering the resulting so formed therapeutic aqueous solution containing dissolved therein said unstable metabolites,

said second composition being a dry powder consisting essentially of at least one material selected from the group consisting of metabolite ketoacids and metabolite sulfhydryl-containing amino acids, said first composition being an aqueous solution containing dissolved therein at least one material selected from the group consisting of (a) inorganic electrolytes, (b) nutrients, and (c) stable metabolites.

2. The filled container prepared by the process of claim 1.

3. A method for administration of a redox active parenteral therapeutic solution comprising the steps of

(A) dissolving in sterile and substantially pyrogen free water inorganic salts and carbon dioxide which are also both sterile and

substantially pyrogen free thereby producing an aqueous solution having the following compositions:

Component	Quantity (in mMoles/Liter)
Na^+	130 - 165
K^+	0 - 5
Ca^{++}	0 - 2.5
Mg^{++}	0 - 1.5
Cl^-	90 - 120
HCO_3^-	25 - 35
CO_2	1.2 - 2

(B) filling a sterile bag having a substantially inert plastic inner wall and having an internal volume ranging from about 0.5 to 3 liters with said solution, said bag being further characterized by being substantially impermeable to carbon dioxide,

(C) sealing said bag,

(D) storing and moving such resulting sealed bag to a location adjacent a patient to whom said solution is to be administered parenterally,

(E) penetrating said bag with a tubular delivery system associated therewith under sterile conditions, and

(F) interconnecting the interior of said bag with said patient under sterile conditions through said delivery system,

4. The method of claim 3 wherein said solution additionally contains from about 0.1 to 45 mM of l-lactate anions.

5. The method of claim 3 wherein said solution additionally contain from about 0.1 to 45 mM of d-betahydroxybutyrate anions.

6. A method for administration of a redox active peritoneal dialysis solution comprising the steps of :

(A) dissolving in sterile and substantially pyrogen free water materials comprising inorganic salts, carbon dioxide and glucose

which materials are also both steril and substantially pyrogen free, thereby to produce an aqueous solution having the following composition:

Component	Quantity (in mMoles/Liter)
Na^+	130 - 165
K^+	0 - 5
Ca^{++}	0 - 2.5
Mg^{++}	0 - 1.5
Cl^-	90 - 120
HCO_3^-	25 - 35
CO_2	1.2 - 2
glucose	80 - 250,

(B) filling a sterile bag having a substantially inert plastic inner wall and having an internal volume ranging from about 0.5 to 3 liters with said solution, said bag being further characterized by being substantially impermeable to carbon dioxide,

(C) sealing said bag,

(D) storing and moving such resulting sealed bag to a location adjacent a patient to whom said solution is to be administered peritoneally,

(E) penetrating said bag with a tubular delivery system under sterile conditions, and

(F) interconnecting the interior of said bag with the peritoneal cavity of said patient through said tubular delivery system, and

(G) transferring under sterile conditions said solution into said peritoneal cavity.

7. The method of claim 6 wherein said solution additionally contains from about 0.1 to 45 mM/liter of l-lactate ions.

8. The method of claim 6 wherein said solution additionally contains from about 0.1 to 45 mM/liter of d-betahydroxybutyrate anions.

9. An article of manufacture comprised of (A) a sterile sealed bag having a substantially inert plastic inner wall and having an internal volume ranging from about 0.5 to 3 liters, said bag also being substantially impermeable to carbon dioxide, (B) said bag further, being filled with a sterile therapeutic aqueous solution having the following composition:

Component	Quantity (in mMoles/Liter)
Na^+	130 - 165
K^+	0 - 5
Ca^{++}	0 - 2.5
Mg^{++}	0 - 1.5
Cl^-	90 - 120
HCO_3^-	25 - 35
CO_2	1.2 - 2

10. The article of claim 9 wherein a sterile delivery means including tube is functionally associated with said bag, and which means is adopted for transfer under sterile conditions of said solution from said bag into a patient to whom said solution is to be administered.

11. The article of claim 9 wherein said solution additionally contains dissolved therein from about 80 to 250 mM glucose.

12. The article of claim 9 wherein said solution contains additionally at least one anion selected from the group consisting of l-lactate and d-betahydroxybutyrate.